

Low dose rate brachytherapy for localised prostate cancer

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg132

1 Guidance

- 1.1 Current evidence on the safety and short- to medium-term efficacy of low dose rate brachytherapy for localised prostate cancer appears adequate to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance.
- 1.2 Most of the evidence on the efficacy of low dose rate brachytherapy for localised prostate cancer relates to the reduction of prostate-specific antigen (PSA) levels and to biopsy findings. The effects on quality of life and long-term survival remain uncertain. Clinicians should ensure that patients understand these uncertainties and the alternative treatment options. Use of the Institute's [information for the public](#) is recommended.
- 1.3 A multidisciplinary team should be involved in the planning and use of this procedure. The Institute has issued a cancer service guideline on [improving outcomes in urological cancers](#).

- 1.4 Further research and audit should address quality of life, clinical outcomes and long-term survival.

2 The procedure

2.1 Indications

- 2.1.1 Treatment options for prostate cancer depend on whether the disease is localised to the prostate gland. Current management options for localised prostate cancer include radiotherapy, radical prostatectomy and 'watchful waiting'.
- 2.1.2 Radiation therapy can take the form of external-beam radiotherapy or brachytherapy. Brachytherapy may be given at either low or high dose rates. Low dose rate brachytherapy may be used alone (monotherapy) or in combination with external-beam radiotherapy.

2.2 Outline of the procedure

- 2.2.1 Low dose brachytherapy is a form of radiotherapy in which radiation is delivered directly to the prostate gland by small radioactive pellets (called seeds).
- 2.2.2 Under general or spinal anaesthesia and ultrasound guidance, the seeds are inserted via needles passed through the skin of the perineum. In low dose rate brachytherapy, the seeds are left in place permanently and emit low-dose radiation over several weeks or months.

2.3 Efficacy

- 2.3.1 The literature search found no randomised controlled trials that compared low dose rate brachytherapy with other kinds of treatment. Evaluation of the effectiveness of brachytherapy was made difficult by the diversity of the techniques used, the patient selection criteria applied and the different follow-up intervals reported.

- 2.3.2 A recent large cohort study that compared almost 3000 patients undergoing low dose rate brachytherapy (either as monotherapy or combined with external-beam radiotherapy) with external-beam radiotherapy (> 72 Gy) or radical prostatectomy, found no difference in biochemical-recurrence-free survival between the three treatments at 5 or 7 years follow-up. In a comparative study in which 869 patients were treated with low dose rate brachytherapy, a 0.5 ng/ml PSA nadir level was reached in 86% (748/869) of patients after therapy. No comparison of long-term effects could be made because the outcomes for patients treated with radical prostatectomy were not recorded beyond 2 years.
- 2.3.3 In a comparative study involving 1819 patients, overall survival at median follow-up of 58 months in patients with T1 or T2 cancer was found to be similar among those undergoing low dose rate brachytherapy (93%; 679/733 patients), radical prostatectomy (97%; 721/746 patients) and external-beam radiotherapy (96%; 325/340 patients).
- 2.3.4 In another study, physical function scores in 92 patients treated with low dose rate brachytherapy and 327 patients treated with radical prostatectomy showed no significant changes from baseline in either group at 24 months. For more details, refer to the Sources of evidence.
- 2.3.5 The Specialist Advisors considered low dose rate brachytherapy to be an established procedure and stated that the results are comparable with those achieved with surgery or external-beam radiotherapy in well-selected patients.

2.4 Safety

- 2.4.1 Complications were generally not well reported, but included irritative/obstructive urinary symptoms, rectal symptoms and sexual dysfunction. In one study involving 869 patients undergoing low dose rate brachytherapy, the impotence rate was 10–15%, compared with 45% in 208 patients undergoing radical prostatectomy. The incontinence rate was less than 1% in both groups.
- 2.4.2 Two case series included in a *Health Technology Assessment Review* reported disease-specific quality of life to be lower in patients receiving

brachytherapy than in both those receiving external-beam radiotherapy alone and those in a healthy population. However, this review did not differentiate between low dose rate and high dose rate brachytherapy. For more details, refer to the Sources of evidence.

- 2.4.3 The Specialist Advisors noted potential complications such as incontinence, infection and erectile dysfunction.

2.5 Other comments

- 2.5.1 The data are difficult to interpret because of the other treatment modalities often used alongside this procedure.
- 2.5.2 In recommending that further research and audit should address long-term survival, it was noted that men with prostate cancer often die from unrelated causes.
- 2.5.3 It was also noted that the appropriate length of long-term follow-up would depend on the stage and grade of the tumour.

3 Further information

- 3.1 The Institute has issued interventional procedure guidance on [laparoscopic radical prostatectomy](#), [high-intensity ultrasound for prostate cancer](#) and [cryotherapy for recurrent prostate cancer](#). It is also preparing guidance on high dose rate brachytherapy [Now published as ['High dose rate brachytherapy in combination with external-beam radiotherapy for localised prostate cancer'](#)].
- 3.2 The Institute is also developing a clinical guideline: *Prostate cancer: diagnosis and treatment* [Now published as ['Prostate cancer: diagnosis and treatment'](#)].

Andrew Dillon
Chief Executive
July 2005

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of low dose rate brachytherapy for localised prostate cancer', January 2005.

Information for patients

NICE has produced information on this procedure for patients and carers. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 Other NICE recommendations on brachytherapy for the treatment of prostate cancer

Further recommendations have been made as part of the clinical guideline on prostate cancer published in February 2008, as follows:

Brachytherapy is not recommended for men with high-risk localised prostate cancer.

Clinical and cost-effectiveness evidence was reviewed in the development of this guideline which has led to this more specific recommendation. More information is available.

The IP guidance on low dose rate brachytherapy for localised prostate cancer remains current, and should be read in conjunction with the clinical guideline.

5 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical

effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedure guidance](#) process.

It has been incorporated into the [NICE pathway on prostate cancer](#), along with other related guidance and products.

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence it is based on is also [available](#).

Changes since publication

23 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).